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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,066	12/03/2003	Athur C. Perry	1987.1-7 (040020)	7966

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CHARMASSON, BUCHACA & LEACH, LLP
1545 HOTEL CIRCLE SOUTH, SUITE 150
SAN DIEGO, CA 92108-3426

EXAMINER

BLANCO, JAVIER G

ART UNIT PAPER NUMBER

3738

DATE MAILED: 07/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No. 10/728,066	Applicant(s) PERRY ET AL.	
	Examiner Javier G. Blanco	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicants' amendment of claims 1-20, 22, 25, and 27 in the reply filed on May 5, 2006 is acknowledged.

Claim Objections

2. Claims 1, 7, and 17 are objected to because of the following informalities:
 - a. Regarding claim 1, please (i) substitute "a first outer surface section of said core; and" (see line 4) with --a first outer surface section of said core;-- (i.e., delete "and"), (ii) substitute "bioabsorbability rate and a second" (see line 6) with --bioabsorbability rate; and a second-- (i.e., add a semicolon in front of "and"). Appropriate correction is required.
 - b. Regarding claim 7, please substitute "and second portions" (see line 1) with --and second coating portions--. Appropriate correction is required.
 - c. Regarding claim 17, please substitute "first portion" (see line 1) with --first coating portion--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 18 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described

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in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

a. Regarding claim 18, the “means for reducing an adverse immune response” (see line 2) is not enabling. The specification does not disclose/describe a structure (means) that will perform (for) the function (reducing an adverse immune response) as required in claim 18. It is noted that the Specification was recently (i.e., May 5, 2006) amended (see page 13, line 1) to include “including adverse immune response reducers”. The specification still does not disclose/describe a structure (means) that will perform (for) the function (reducing an adverse immune response) as required in claim 18. Also, the Specification does not describe what are the “adverse immune response reducers”.

b. Regarding claim 23, the “means for reducing an adverse immune response” (see line 2) is not enabling. The specification does not disclose/describe a structure (means) that will perform (for) the function (reducing an adverse immune response) as required in claim 23. It is noted that the Specification was recently (i.e., May 5, 2006) amended (see page 13, line 1) to include “including adverse immune response reducers”. The specification still does not disclose/describe a structure (means) that will perform (for) the function (reducing an adverse immune response) as required in claim 23. Also, the Specification does not describe what are the “adverse immune response reducers”.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding claim 2 the limitation “said coating” (see line 1) is indefinite as to the scope of the invention and it lacks antecedent basis. By “the coating”, is said limitation referring to another coating? To which coating (i.e., “first coating portion”, or “second coating portion”) is that limitation referring?

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-10 and 12-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Perry (WO 94/14390 A1).

Referring to Figures 1, 3, and 4, Perry discloses an orbital implant comprising:

(i) a substantially spheroid body *sized and shaped to be placed* (emphasis added to functional language) in the orbit;

(ii) a coating (“coated” or “wrapped”: see page 5, lines 23-29; page 13, line 34 to page 14, line 2) *sized and shaped to intimately contact* (emphasis added to functional language) a section of said body; and wherein said coating has a first portion having a first bioabsorbability and a second portion having a second bioabsorbability different from said first bioabsorbability. The orbital

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implant may be coated/impregnated with a first bioabsorbable portion/material (e.g., a vascularization agent) prior to (see page 16, lines 31-35; page 17, lines 4-6) or after (see page 17, lines 7-13) applying a second bioabsorbable portion/material (e.g., collagen, polyglycolic acid, or polylactic acid coating/wrapping), which subject matter is not only well known in the art but is further disclosed at page 22, lines 4-14. Chemical and/or molecular bonds keep said first and second portions/materials bonded.

The bioabsorbable (see page 12, lines 5-26) coating/wrapping materials are disclosed as not causing undue adverse immune response (see page 11, lines 19-24). The coating/wrapping may further include therapeutic agents (see page 13, lines 7-8; page 14, lines 14-29), color-coding indicia (see page 22, lines 15-18), passageways *sized to allow* (emphasis added to functional language) fluid exchange therethrough (see page 16, lines 25-29; page 23, lines 34-37; page 28, lines 19-23), a surface having microtexturing (see page 14, lines 31-36; page 24, lines 14-15) and/or an outer surface which is smoother than a first surface (see page 12, lines 27-29; page 14, lines 31-36; page 24, lines 15-17), a thickness of less than one millimeter (see page 12, lines 27-29), and a thickness *selected to allow melting penetration* (emphasis added to functional language) using a handheld cautery (see page 29, lines 11-14).

Response to Arguments

9. Applicants' arguments filed May 5, 2006 have been fully considered but they are not persuasive.

The Applicants argue that Perry (WO 94/14390 A1) does not disclose two coating portions "*covering two distinct sections of the implant*" (emphasis added) and that "*nowhere*

does it disclose fractional coating areas” (emphasis added). It is noted that this language is not part of the language of independent claims 1, 20, and 22.

As previously indicated in the 102(b) rejection, the orbital implant may be coated/impregnated with a first bioabsorbable portion/material (e.g., a vascularization agent) prior to (see page 16, lines 31-35; page 17, lines 4-6) or after (see page 17, lines 7-13) applying a second bioabsorbable portion/material (e.g., collagen, polyglycolic acid, or polylactic acid coating/wrapping), which subject matter is not only well known in the art but is further disclosed at page 22, lines 4-14. The vascularization agent coating/wrapping will have a bioabsorbability rate/property. The biopolymer (e.g., collagen, polyglycolic acid, or polylactic acid) coating/wrapping will have a bioabsorbability rate/property different than the one from the vascularization agent coating/wrapping. The two coatings/wrappings are “separate” since they are not blended/mixed. Also, the two coatings/wrappings are “separate” since they are coated/wrapped at different time frames. Each of said coatings/wrappings will be covering (directly or indirectly) first and second outer surface sections of the porous core.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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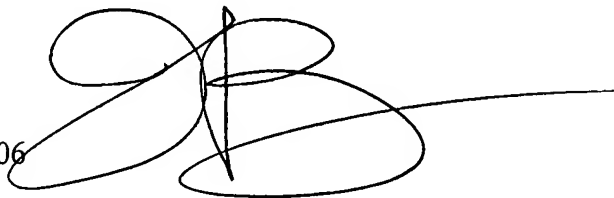

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

July 12, 2006

A large, stylized handwritten signature in black ink, likely belonging to Javier G. Blanco, the examiner mentioned in the text.A handwritten signature in black ink, likely belonging to David H. Willse, the Primary Examiner.

David H. Willse
Primary Examiner